



## **DEPARTMENT OF AGRICULTURE**

### **Agricultural Marketing Service**

#### **7 CFR Part 205**

**[Document Number AMS-NOP-10-0079; NOP-09-02FR]**

RIN 0581-AD06

National Organic Program (NOP); Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing)

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to enact six recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on May 22, 2008, November 19, 2008, and May 6, 2009. This final rule adds one substance, microcrystalline cheesewax, along with any restrictive annotations, for use in organic mushroom production; and adds three substances, acidified sodium chlorite, dried orange pulp, and Pacific kombu seaweed, with any restrictive annotations, for use in organic handling. This final rule also amends the annotation for one substance used in organic handling, unbleached lecithin, and removes bleached lecithin from the National List.

**EFFECTIVE DATE:** This rule becomes effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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## **SUPPLEMENTARY INFORMATION:**

### **I. Background.**

On December 21, 2000, the Secretary established within the NOP [7 CFR part 205] the National List regulations §§ 205.600 through 205.607. The National List identifies synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies nonagricultural synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 et seq), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic, nonagricultural substance used in organic handling must also be on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the NOP has published multiple amendments to the National List: October 31, 2003 (68 FR 61987); November 3, 2003 (68 FR 62215); October 21, 2005 (70 FR 61217); June 7, 2006 (71 FR 32803); September 11, 2006 (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007 (72 FR 58469); December 10, 2007 (72 FR 69569); December 12, 2007 (72 FR 70479); September 18, 2008 (73 FR 54057); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919); December 13, 2010 (75 FR 77521) and March 14, 2011 (76 FR 13501). Additionally, a proposed amendment to the National List was published on May 5, 2011 (76 FR 25612).

This final rule amends the National list to enact six recommendations submitted to the Secretary by the NOSB on May 22, 2008, November 19, 2008, and May 6, 2009.

## II. Overview of Amendments

The following provides an overview of the amendments made to designated sections of the National List regulations:

### Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

This final rule amends § 205.601 of the National List regulations by adding new paragraph (o) for the addition of one substance as follows: As production aids.

Microcrystalline cheesewax (CAS #s 64742- 42-3, 8009-03-08, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

The proposed rule to add microcrystalline cheesewax included an annotation specifying that the substance be “for use in log grown mushroom culture.” The NOP determined that the substance’s use annotation should be modified “for use in log grown mushroom production” (emphasis added) in this final rule. This language change is consistent with terminology that will be utilized in a forthcoming proposed rule on organic mushroom standards.

### Section 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

This final rule amends § 205.605(b) of the National List regulations by removing Lecithin—bleached, and adding acidified sodium chlorite in alphabetical order as follows: Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Section 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

This final rule amends § 205.606 of the National List regulations by revising paragraph (p) to read as follows: (p) Lecithin—de-oiled. Further, this final rule redesignates paragraphs (r) through (t) and paragraphs (u) through (y) as paragraphs (s) through (u) and (w) through (aa) respectively; and adds new paragraphs (r) and (v) for the addition of two substances as follows: (r) Orange pulp, dried, and (v) Seaweed, Pacific kombu.

III. Related Documents.

Three notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following Federal Register notices: (1) 74 FR 11904, March 20, 2009 (bleached lecithin, acidified sodium chlorite, unbleached fluid lecithin); (2) 73 FR 54781, September 23, 2008 (dried orange pulp, acidified sodium chlorite); and (3) 73 FR 18491, April 4, 2008 (microcrystalline cheesewax, acidified sodium chlorite, Pacific kombu seaweed). The proposal to allow the use of the four substances in this final rule, along with the deletion of one substance and the revised annotation of one substance, was published as a proposed rule on November 8, 2010 (75 FR 68505).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501-6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process

by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget (OMB).

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such

additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601-624), the Poultry Products Inspection Act (21 U.S.C. 451-471), or the Egg Products Inspection Act (21 U.S.C. 1031-1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

### C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to

certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this final rule would not be significant. The effect of this final rule would be to allow the use of additional substances and clarify the use of one substance in agricultural production and handling. This action will modify the regulations published in the final rule and will provide small entities with more tools to use in day-to-day farming and handling operations. AMS concludes that the economic impact of this addition of allowed substances, if any, will be minimal and beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000.

According to USDA Economic Research Service (ERS) data based upon information from USDA-accredited certifying agents, the number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.<sup>1</sup> ERS, based upon the list of certified operations maintained by the National Organic

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<sup>1</sup> U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992-2008*. <http://www.ers.usda.gov/Data/Organic/>

Program, estimated the number of certified handling operations was 3,225 in 2007.<sup>2</sup> The AMS believes that most of these entities would be considered to be small entities under the criteria established by the SBA.

The U.S. sales of organic food and beverages grew from \$3.6 billion in 1997 to nearly \$21.1 billion in 2008.<sup>3</sup> Between 1990 and 2008, organic food sales demonstrated an historic growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.<sup>4</sup>

In addition, USDA has 93 accredited certifying agents (ACA) who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of ACAs may be found on the AMS NOP website, at <http://www.ams.usda.gov/nop>. The AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

#### D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

#### E. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

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<sup>2</sup> U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation*. <http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm>

<sup>3</sup> Dimitri, C., and L. Oberholtzer. 2009. Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers, Economic Information Information bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, <http://www.ers.usda.gov/PublicationsE1B58>.

<sup>4</sup> Organic Trade Association's 2011 Organic Industry Survey, <http://www.ota.com>.



#### F. Comments Received on Proposed Rule NOP-09-02

AMS received 11 comments on the proposed rule AMS-NOP-10-0079; NOP-09-02PR. Comments were received from specialty food ingredient processors and distributors, specialty food products manufacturers, an industrial sanitation supply firm, an organic consultant, a coalition of foreign governments and a private citizen. Comments were submitted in support of the proposed additions to the National List for all four of the proposed new use exemptions and the deletion of one substance. Comments in favor of the addition of acidified sodium chlorite to § 205.605(b) stated that it will increase the intervention options available for maintaining high sanitation standards in organic food processing and thereby further improve food safety for consumers of organic processed foods. While one comment expressed concern about the proposed exemption for the secondary direct antimicrobial food treatment use of acidified sodium chlorite, the commenter did not take a position for or against the specific proposal. A comment endorsing the addition of dried orange pulp to § 205.606 stated that its use is consistent with organic principles, since an insufficient volume of organic oranges are grown and processed to produce organic orange pulp, which is a byproduct of extraction orange juice processing.

Many comments addressed the proposed change in the lecithin annotation from unbleached to de-oiled on § 205.606. Nonorganic forms of the substances listed under § 205.606 are allowed as ingredients in or on processed products labeled as organic only when the nonorganic substance is not commercially available in organic form and only in accordance with any specified restrictions. Most comments submitted in support of the lecithin annotation change stated that the listing of de-oiled lecithin on § 205.606 would prevent disruption in the availability or quality of a broad range of organic food products such as ice cream, pasta, bakery goods, cereals, sauces, soups and frozen desserts. They indicated that de-oiled is the appropriate

annotation because this form of lecithin has a unique function and blander flavor in comparison to fluid or dry lecithin. The comments mentioned de-oiled lecithin's superiority in maintaining stability of water and oil emulsions. Furthermore, the comments informed that de-oiled lecithin is not available as organic.

Comments in support of removing bleached lecithin from § 205.605(b) indicated that this action will encourage the increased production and use of organic ingredients needed for organic food processing. They also argued that unbleached lecithin is now commercially available in organic forms, so the exemption for these substances is no longer crucial. Commenters stated that the use of nonorganic de-oiled lecithin on § 205.606, instead of the nonorganic unbleached form previously allowed, would be subject to the determination of commercial availability of any organic form - once developed - in the processor's organic system plan and other specific restrictions. Commenters in favor of the amendment expressed frustration with discrepant use of organic unbleached lecithin and less expensive conventional unbleached lecithin in comparably priced multiple brands of the same processed organic products on retail shelves. These commenters conveyed expectations that this rule change will result in the replacement of nonorganic bleached lecithin with the organic form and thus encourage increased use and availability of organic ingredients.

A few comments opposing the change in the unbleached lecithin annotation at § 205.606 explained that the only current source of organic lecithin is soy, which is a food allergen. They cited a lack of availability of organic forms of lecithin from sunflower or canola and predicted that consumers with a soy allergy would not be able to eat organic products containing soy lecithin. These commenters noted that soy is identified in the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) (21 U.S.C. 301) as one of 8

major food groups which account for 90 percent of life-threatening food allergies. This legislation established mandatory disclosure requirements on labels for processed food containing any amounts of the eight named foods (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) listed in the 2004 Act. Food processors have become more aware of soy's allergenic potential and the federal labeling requirements when soy-based ingredients are used since passage of the 2004 Act. The opposing comments expressed concern that the annotation change would result in higher levels of soy lecithin being used in processed organic foods because it is more commonly available in organic form, but did not provide specific evidence to support this statement. Nonorganic lecithin from sunflower, rapeseed and canola is widely available commercially, and NOP believes that there is potential that any increased demand for non-soy lecithin will stimulate increased production of organic forms of bleached and unbleached lecithin from these alternative sources.

A comment criticized the NOSB for omitting food allergies from the discussion in considering the lecithin petition. The NOSB did address this issue several times during its deliberation, as captured in the May 2009 NOSB meeting transcripts. The Board concluded that its recommended change to unbleached lecithin would still avail manufacturers with the option to use nonorganic, non-soy forms of de-oiled lecithin. Commenters conveyed a preference to have non-allergenic, nonorganic forms of lecithin available under § 205.606. The change in annotation does not specify the plant source of lecithin and, therefore, nonorganic de-oiled lecithin from non-soy and nonorganic sources may be used when organic equivalents are not available. A substance is considered commercially available if it is available in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. In

summary, this annotation change would not limit the use of lecithin to organic de-oiled soy lecithin. Non-soy sources that are non-GMO and nonorganic would remain acceptable under § 205.606, and accredited certifying agents would continue to require any nonorganic de-oiled lecithin to be sourced from non-GMO sources as long as de-oiled lecithin is not commercially available in organic form.

#### Changes Requested But Not Made

Commenters requested that the proposed action be amended for § 205.606 to allow the use of non-GMO, non-allergenic lecithin. We have not made that change because we believe this request is mostly accommodated by the proposed action. Nonorganic forms of de-oiled lecithin can be used when the organic version is not commercially available. The NOP regulations define commercially available as a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan. Therefore, if a processor intends to make a soy-free product containing lecithin, in which de-oiled is the appropriate form, the processor may use nonorganic de-oiled lecithin from sunflower, canola or other sources if lecithin from the preferred sources is not available in organic form. If a product requires a form of lecithin other than de-oiled, such as fluid or powdered, the lecithin must be sourced organically. The NOSB recommendation was finalized in May 2009. We believe that processors have had adequate notice to pursue the procurement of non-soy forms of organic lecithin if their products are intended to be soy free.

## List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, subpart G is amended as follows:

### PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

2. In § 205.601 add new paragraph (o) to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

\* \* \* \* \*

(o) As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)—for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

\* \* \* \* \*

3. Section 205.605 is amended by:

A. Removing “Lecithin-bleached” from paragraph (b); and

B. Adding one new substance “Acidified sodium chlorite”, in alphabetical order, to paragraph (b) to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

\* \* \* \* \*

(b) \* \* \*

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

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4. Section 205.606 is amended by:

A. Revising paragraph (p);

B. Redesignating paragraphs (r) through (t) and paragraphs (u) through (y) as paragraphs (s) through (u) and (w) through (aa) respectively; and

C. Adding new paragraphs (r) and (v).

The revisions read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

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(p) Lecithin—de-oiled.

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(r) Orange pulp, dried.

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(v) Seaweed, Pacific kombu.

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Dated: February 3, 2012

Robert C. Keeney  
Acting Administrator  
Agricultural Marketing Service

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